for deposit to the special account ''Salaries and Expenses, Certification, Inspection, and Other Services, Food and Drug Administration.''

[39 FR 18934, May 30, 1974, as amended at 40 FR 13497, Mar. 27, 1975; 40 FR 28052, July 3, 1975; 41 FR 2384, Jan. 16, 1976; 41 FR 18291, May 3, 1976; 44 FR 67113, Nov. 23, 1979; 45 FR 16471, Mar. 14, 1980; 46 FR 16677, Mar. 13, 1981; 46 FR 60578, Dec. 11, 1981; 46 FR 61071, Dec. 15, 1981; 50 FR 19918, May 13, 1985; 55 FR 11582, Mar. 29, 1990]

Subpart C—Records and Reports

§ 431.61 Records of distribution.

(a) The person who requested certification shall keep complete records showing each shipment and other delivery (including exports) of each certified batch or part thereof by such person or by any person subject to his control. Such records shall show the date and quantity of each such shipment or delivery and the name and post-office address of the person to whom such shipment or delivery was made, and shall be kept for not less than 3 years after such date.

(b) Upon the request of any officer or employee of the Food and Drug Administration, or of any other officer or employee of the United States acting on behalf of the Secretary, the person to whom a certificate is issued shall at all reasonable hours make such records available to any such officer or employee and shall accord to him full opportunity to make inventory of stocks of such batch on hand and otherwise to check the correctness of such records.

§ 431.62 Records retention.

At the option of the person having control of records required to be kept by any regulation in this part 431, photostatic or other permanent reproductions may be substituted for such records after the first 2 years of the holding period.

Subpart D—Confidentiality of Information

§ 431.70 Confidentiality of data and information in an investigational new drug notice for an antibiotic drug.

(a) The existence of an IND notice for an antibiotic drug will not be disclosed by the Food and Drug Administration unless it has previously been publicly disclosed or acknowledged.

(b) The availability for public disclosure of all data and information in an IND file for an antibiotic drug shall be handled in accordance with the provisions established in § 314.430 of this chapter.

(c) Notwithstanding the provisions of § 314.430 of this chapter, the Food and Drug Administration shall disclose upon request to an individual on whom an investigational antibiotic has been used a copy of any adverse reaction report relating to such use.

[39 FR 44655, Dec. 24, 1974, as amended at 50 FR 7517, Feb. 22, 1985]

PART 432—PACKAGING AND LABELING OF ANTIBIOTIC DRUGS

Sec.

AUTHORITY: Secs. 201, 301, 502, 503, 507, 701, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 352, 353, 357, 371, 381).

CROSS REFERENCE: For other regulations in this chapter concerning antibiotic drugs exempted from certain labeling requirements, see also § 201.150 of this chapter.

§ 432.1 Packaging requirements.

Each antibiotic drug subject to certification under section 507 or 512(n) of the act shall be packaged in immediate containers which shall be of such composition as not to cause any change in the strength, quality, or purity of the contents beyond any limits therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The immediate containers shall be tight containers as defined by the U.S.P., except that if the antibiotic drug is dispensed as an ointment or cream, the immediate containers shall be well-closed containers as defined by the U.S.P. If the antibiotic drug is packaged for dispensing, it may be packaged in combination with a container of a suitable and